UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ROCHESTER DRUG COOPERATIVE, INC., on behalf of itself and all others similarly situated, Plaintiff, v. JOHNSON & JOHNSON and JANSSEN BIOTECH, INC., Defendants.	Civil Action No. CLASS ACTION JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

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Direct Purchaser Plaintiff Rochester Drug Cooperative, Inc. (RDC) brings this class action, on behalf of itself and all others similarly situated, against Defendants Johnson & Johnson and Janssen Biotech, Inc. (together, "J&J"). Based on personal knowledge, the investigation of counsel, and information and belief, Plaintiff alleges as follows:

I. INTRODUCTION

1. For many years, J&J was the only seller of infliximab in the United States and J&J's infliximab product Remicade enjoyed strong sales and profits. When J&J learned that competing biosimilar versions of infliximab were coming to market, J&J decided not to compete on the merits. Instead, J&J launched the exclusionary scheme described herein which was designed to shield J&J's Remicade from competition and anticompetitively maintain J&J's infliximab market dominance.

2. Infliximab is a biologic infusion drug designed to inhibit specific components of the immune system that play pivotal roles in fueling inflammation, and thus is an important therapy for treating many common conditions, including rheumatoid arthritis and Crohn's disease. Infliximab cannot be administered orally because the human digestive system can destroy the drug. Thus, infliximab is generally given by intravenous infusion by a healthcare provider in-office (*e.g.*, at an infusion center or a hospital). Each infusion typically takes more than an hour and infusions are often given on a routine basis due to the chronic nature of the conditions that infliximab is designed to treat.

3. The U.S. Food and Drug Administration (FDA) approved infliximab for sale in the United States in 1998.

4. For many years, J&J was the sole seller of infliximab in the United States. J&J sells infliximab under the name Remicade. It is J&J's top-selling drug and among the top selling drugs of all time.

5. Remicade is expensive. At list price Remicade sells for about $4,000 per infused dose and about $26,000 for a full year of treatment. In 2016 alone, it generated approximately $4.8 billion in United States sales for J&J.

6. In 2009, Congress, through the Biologics Price Competition and Innovation Act of 2009 (BPCIA), created an abbreviated licensure pathway for biosimilar biological products. This pathway was established as a way to provide more treatment options, increase access to lifesaving medications, and lower health care costs through competition.

7. As explained in greater detail below, a biosimilar is like a generic version of a branded pharmaceutical product (*i.e.*, a biosimilar is to Remicade what the generic drug atorvastatin is to the branded drug Lipitor). The FDA considers biosimilar products to have "no clinically meaningful differences in terms of safety and effectiveness from the reference product."[1]

8. Remicade faced no competition until April 2016. Since April 2016, the FDA has approved three Remicade biosimilars (*i.e.*, products with "no clinically meaningful differences" to J&J's Remicade):

- Inflectra (infliximab) was approved in April 2016. Inflectra is marketed by Pfizer.
- Renflexis (infliximab) was approved in April 2017. Renflexis is marketed by Samsung.
- Ixifi (infliximab) was approved in December 2017. Ixifi is owned by Pfizer, but it has not yet been commercially launched.

9. Competition typically leads to lower prices. This is axiomatic. But this was not the case in the market for infliximab upon entry of biosimilars. Despite the entries of these

[1] FDA Website, Information on Biosimilars, *available at* https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/.

competing biosimilar infliximab products at substantially lower prices, J&J has maintained and increased its pricing for its infliximab product Remicade.

10. J&J did not achieve this unusual result by competition on the merits, but instead through a multifaceted scheme to block biosimilar competition to Remicade through a web of exclusive dealing contracts. J&J's scheme impacted multiple levels of the distribution chain, targeting both insurers and healthcare providers, and involved exclusive deals for Remicade, multi-product bundled rebates, rebates based on the bundling of new and existing patients, and other anticompetitive activities designed to prevent infliximab biosimilars from gaining business no matter how much lower their prices.

11. J&J dubbed its scheme the "Biosimilar Readiness Plan. The "Biosimilar Readiness Plan" consisted of, among other things:

i. imposing biosimilar-exclusion provisions on insurers designed to prevent provider reimbursement for non-J&J infliximab products;

ii. bundling "contestable" and "incontestable" infliximab demand at the insurer level; and

iii. multiproduct bundling of J&J's Remicade with other J&J drugs and medical devices at both the insurer and provider levels (including drugs and medical devices that J&J's competitors did not sell).

12. J&J's Biosimilar Readiness Plan foreclosed opportunities for biosimilar versions of infliximab to compete with J&J's Remicade. J&J's Biosimilar Readiness Plan was designed to (and did) prevent and inhibit insurers and providers from purchasing non-J&J infliximab products. In essence, J&J said to insurers: Do not cover biosimilar versions of Remicade (*e.g.*, Inflectra, Renflexis) or you will jeopardize your relationship with J&J, including your ability to get

substantial rebate payments on Remicade and other J&J products. J&J communicated a similar message to healthcare providers.

13. As J&J's CFO stated at a recent investor conference in response to a question about why infliximab biosimilars had not taken as much market share as expected: "I think we did a pretty good job of contracting for Remicade well in advance of the biosimilar entry . . . and we have enough of a robust portfolio of products . . . where we can obviously contract appropriately, and so that was well done by our team."[2]

14. In September 2017, Pfizer filed an antitrust case against J&J alleging that Pfizer had been damaged by J&J's scheme.

15. Pfizer is not alone. As a result of J&J's Biosimilar Readiness Plan (*i.e.*, J&J's scheme to impose a web of exclusive dealing contracts,), direct purchasers of infliximab paid, and continue to pay, supracompetitive prices for infliximab products.

16. RDC, on behalf of itself and members of a proposed direct purchaser class, seeks damages caused by Defendants' antitrust violations.

II. JURISDICTION AND VENUE

17. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and sections 3, 4, and 16 of the Clayton Act, 15 U.S.C. §§ 14, 15, and 26, and seeks to recover threefold damages, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiff and members of the Class (defined below) resulting from Defendants' unlawful impairment of generic competition. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), and 15 U.S.C. § 15.

18. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C.

[2] Morgan Stanley Healthcare Conference Transcript (Sept. 13, 2017).

§§ 1391(b), (c), and (d). During the Class Period, Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of the activity affecting interstate trade and commerce discussed below has been carried out in this District.

19. Defendants' conduct, as described in this complaint, was within the flow of, was intended to, and did have a substantial effect on the interstate commerce of the United States, including this District.

20. During the Class Period, Defendants manufactured, sold and shipped Remicade in a continuous and uninterrupted flow of interstate commerce. The unlawful conduct in which the Defendants engaged had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

21. During the Class Period each Defendant, or one or more of its affiliates, used the instrumentalities of interstate commerce, including interstate wires, interstate electromagnetic spectrum, interstate railways, and the United States mail, to effect their unlawful conduct.

22. This Court has personal jurisdiction over each Defendant because each Defendant – throughout the United States and including in this District – transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of their unlawful scheme and conspiracy. Defendants' unlawful conduct was directed at, and had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

III. PARTIES

A. Plaintiff

23. Plaintiff Rochester Drug Cooperative, Inc. (RDC) is a stock corporation duly formed and existing under the New York Cooperative Corporations Law, with its principal place of business at 50 Jet View Drive, Rochester, New York 14624. During the Class Period, as defined

below, RDC purchased Remicade directly from Defendants, and was injured as a result of Defendants' unlawful conduct.

B. Defendants

24. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business at 1 J&J Plaza, New Brunswick, New Jersey 08933.

25. Defendant Janssen Biotech, Inc. (Janssen) is a wholly owned subsidiary of Johnson & Johnson. Janssen is a Pennsylvania corporation with its principal place of business at 800 Ridgeview Drive, Horsham, Pennsylvania 19044.

26. Johnson & Jonson and Janssen are together referred to as Defendants or "J&J."

IV. THE PRESCRIPTION PHARMACEUTICAL MARKETPLACE AND REGULATORY FRAMEWORK

A. Biologics, Infusions, and Biosimilars

27. As opposed to many pharmaceutical products that are chemically synthesized, biologics are derived from natural sources.[3] Biologics include products such as vaccines, blood and blood products, allergenic extracts, human cells and tissues, gene therapies, and cellular therapies.

28. Although biologics are one of the fastest-growing drug categories in the United States, they are not new. For example, the Biologics Control Act was passed in 1902 and was aimed at ensuring the safety of vaccines.

29. Biologics tend to include delicate molecules such as whole cells, antibodies, or enzymes. As a result, you are unlikely to find biologics in a tablet form because they tend to only

[3] FDA Website, What Are "Biologics" Questions and Answers, *available at* https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm.

survive in a liquid solution. The human digestive system also poses a threat to biologic products and, as a result, many biologics are given by injection or infusion.

30. Biologics also tend to target diseases that no chemically synthesized drug can. For example, biologics are available to treat different forms of cancer, Lupus, rheumatoid arthritis, multiple sclerosis, Crohn's disease, and more. This means that there is high inelastic demand for certain biologics. Further, unlike many pharmaceutical products that are available at lower cost in generic form, a similar "generic" form of a biologic did not exist until very recently.

31. These factors have led to some biologic manufacturers setting very high prices for these drugs (*e.g.*, J&J's Remicade).

B. The Biologics Price Competition and Innovation Act was Intended to Ease Regulatory Hurdles for Biosimilar Pharmaceuticals, Much Like Hatch-Waxman Did for Generic Drugs Many Years Ago

32. The Patient Protection and Affordable Care Act, signed into law by President Obama on March 23, 2010, amends the Public Health Service Act (PHS Act) to create an abbreviated approval pathway for biological products that are demonstrated to be "highly similar" (biosimilar) to or "interchangeable" with an FDA-approved biological product. These new statutory provisions are referred to as the BPCIA (Biologics Price Competition and Innovation Act).

33. Congress recognized the growing importance of biologic pharmaceuticals, as well as the growing costs associated with them, and passed the BPCIA in 2010. The purpose of the BPCIA is to foster meaningful price competition for long-entrenched branded biologic products, with the goal of lowering healthcare costs. To facilitate price competition, the BPCIA provides an abbreviated FDA approval pathway for "biosimilar" versions of branded biologic drugs.

34. The goal of the BPCIA is similar, in concept, to that of the Drug Price Competition

and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), which created abbreviated pathways for the approval of generic drugs. The Hatch-Waxman Act is widely regarded as having brought many additional generic pharmaceuticals to American consumers resulting in many billions of dollars of cost savings. The BPCIA has a similar goal. The BPCIA aligns with the FDA's longstanding policy of permitting appropriate reliance on what is already known about a given drug in seeking approval of a similar drug, thereby saving time and resources and avoiding unnecessary duplication of human or animal testing.

35. Under the BPCIA, a sponsor may seek approval of a "biosimilar" product and such approval will be granted so long as there are no clinically meaningful differences between the biosimilar product and the reference product in terms of safety, purity, and potency. Thus, biosimilars are products that the FDA has determined to have "no clinically meaningful differences" from the already approved biologic (sometimes referred to as the "reference listed drug" or "RLD") in terms of safety, purity, and potency.

36. In 2014, the FDA noted that: "Administration of a biologic agent to an individual patient ranges between $15,000 and $150,000 per year."[4] The FDA called on the pharmaceutical industry to bring biosimilar drugs to market to lower costs for all Americans.

37. As noted above, in 2016 and 2017, Inflectra, Renflexis, and Ixifi were FDA-approved as "biosimilar" to Remicade.

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[4] Epstein et al., *Biosimilars: The Need, The Challenge, The Future: The FDA Perspective*, THE AMERICAN JOURNAL OF GASTROENTEROLOGY (2014), *available at* https://www.nature.com/articles/ajg2014151; Ian Haydon, *Biologics: The Pricey Drugs Transforming Medicine*, SCIENTIFIC AMERICAN (July 26, 2007), *available at* https://www.scientificamerican.com/article/biologics-the-pricey-drugs-transforming-medicine/.

V. J&J'S EXCLUSIONARY SCHEME

A. Insurance Coverage is Critical for Biologic Infusion Products Such as Infliximab

38. Insurance coverage and reimbursement are key to the adoption of biologic infusion products because expensive biologic drugs (like Remicade) will likely not be paid for out of pocket by patients. Most of the patients who are prescribed Remicade have insurance or qualify for patient assistance.

39. Because a biologic infusion product is not one that can be picked up at a pharmacy, but is administered intravenously in a clinic or other institutional setting, it generally is not included under the "pharmacy benefit" of most health plans.

40. In the pharmacy benefit setting, physicians prescribe a drug and the patient procures the medication himself or herself at the pharmacy, paying for it with a combination of insurance coverage (either private or government-sponsored) and an out-of-pocket payment (usually a co-pay). In the pharmacy benefit context, neither the prescribing physician nor the institution with which the physician is affiliated bears financial risk with respect to the drug selected, *i.e.*, the drug is not purchased and stocked in advance by providers at their own cost. The pharmacy buys the drug, dispenses it, and is reimbursed.

41. By contrast, infusion products such as infliximab (sometimes referred to as "medical benefit" products) are administered at a clinic or other healthcare provider site. Unlike with many other drugs where the patient purchases the drug at a pharmacy, the provider purchases the biologic infusion product to administer to patients. The provider later seeks reimbursement for the biologic infusion product from an insurer or third-party payer (a practice commonly referred to as "buy and bill").

42. Thus, when an infusion product is administered by a provider, the provider must secure payment for the service including the cost of the biologic infusion product dispensed (which

the provider had to pay up front with its own funds). In this context, the provider has a strong interest in utilizing biologic infusion products that are widely covered by insurance (particularly by the major national commercial health insurers and significant regional insurers active in its area) to ensure that the provider recoups its significant expense in purchasing the biologic infusion product. If a biologic infusion product is not widely covered, such that there is a risk that coverage might be denied (and providers thus would be burdened with a potential financial loss for what they paid for the biologic infusion product), providers are much less likely to purchase that product – a response that is in line with the providers' economic interests (to be reimbursed).

43. Commercial insurers typically publish medical policies enumerating the biologic infusion products they will cover under the medical benefit and the terms under which they will do so. For example, medical policies may exclude biologic infusion products from coverage or they may dictate restrictions on use. Biologic infusion product and other infusion product manufacturers compete to obtain coverage under insurer medical policies and to have either fewer restrictions on reimbursement than their competitors or, at a minimum, to achieve "parity," whereby competing infusion products have the same restrictions on reimbursement. Securing parity placement is important, especially for new infusion products seeking to gain traction in the marketplace, and particularly with large insurers, which have tens of millions of covered patients.

44. Given the high cost of infliximab products (*e.g.*, Remicade costs thousands of dollars per treatment), providers rarely pay for an infliximab product that they are not confident will be reimbursed by an insurer after the provider administers it to a patient.[5]

[5] The provider has theoretical recourse against the patient where coverage is denied, but the prospect of securing payment in full from the patient is bleak, especially for drugs as costly as Remicade. As a result, where a significant portion of a provider's patients are insured by plans that have agreed to exclude biosimilars to Remicade (*e.g.*, Inflectra, Renflexis) - pursuant to the types

B. J&J's Scheme – The Biosimilar Readiness Plan

45. J&J was well-aware that entry of Remicade biosimilars (such as Pfizer's Inflectra and Samsung's Renflexis) could quickly erode J&J's stranglehold on the market for infliximab. For example, it had seen Remicade sales fall dramatically in Europe upon the entry of biosimilars.

46. Thus, when J&J became aware that infliximab biosimilars were coming to market in the United States, J&J had a choice. J&J could compete with infliximab biosimilars on the merits, as antitrust law requires, or maintain its monopoly through anticompetitive contracts designed to foreclose competition on the merits. J&J chose the latter - dubbed the "Biosimilar Readiness Plan" - by setting up a web of exclusive dealing contracts with insurers, hospitals, and clinics designed to prevent, inhibit, and foreclose these customers from purchasing non-J&J infliximab products.

47. Under the Biosimilar Readiness Plan, J&J, among other things, effectively said to insurers: if you want to have infliximab biosimilars on your formulary, Remicade and other J&J products are going to cost you, the insurer, a lot more money than they otherwise would. J&J sent a similar message to healthcare providers.

48. As stated by J&J's Worldwide Chairman for Pharmaceuticals Joaquin Duato in an October 2016 earnings call (the day after Pfizer's Inflectra launched): "We are fully prepared to execute our focused biosimilar readiness plan." Duato went on to note that he was confident in J&J's strategy for various reasons including that "70% of patients who are stable on Remicade are highly unlike to switch [to a biosimilar]" and "in developing innovative contracts, we can utilize the full breadth of our portfolio."

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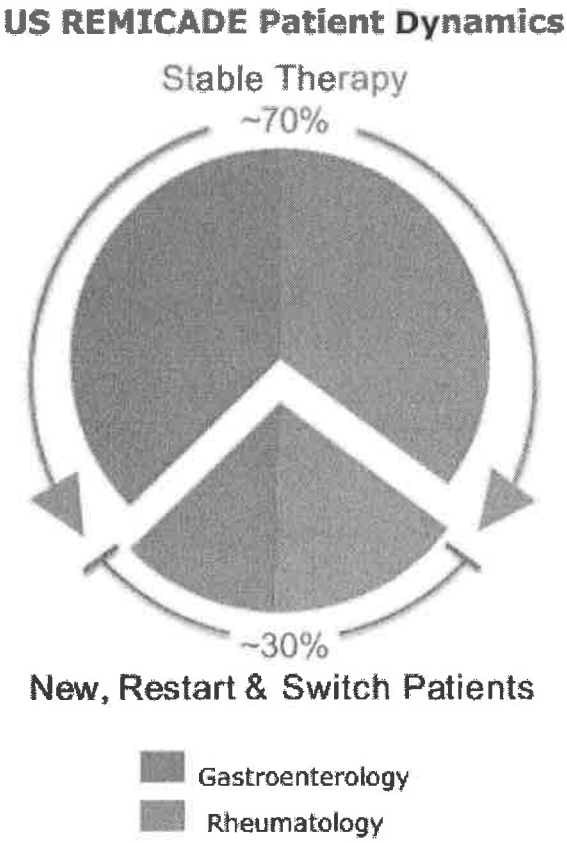
of contracts described above - the provider is unlikely to offer the competing products to any of its patients to avoid being caught with no reimbursement.

49. The slideshow accompanying the J&J October 2016 earnings call stated: "Our US REMICADE® Biosimilar Readiness Plan Is In Place" and J&J is "[p]repared to compete with a new entrant in an already competitive environment [because J&J] [d]eveloped a range of innovative contracting options that draw on full breadth of the Johnson & Johnson portfolio." This slideshow also noted United States Remicade patients consisted of 70% patients who are stable on Remicade and 30% patients who are new, restart, or switch patients:



50. Duato's comments were also echoed in a contemporaneous corporate statement from J&J concerning the Remicade biosimilar launch: "We intend to compete through a variety of innovative contracting options, discounts and rebates[.]"[6]

[6] Bill Berkrot, *Pfizer to start shipping biosimilar version of J&J's Remicade in November*, REUTERS (Oct. 17, 2016), *available at* https://www.reuters.com/article/us-pfizer-biosimilar/pfizer-to-start-shipping-biosimilar-version-of-jjs-remicade-in-november-idUSKBN12H2FZ.

51. Analysts and commentators noted that J&J was "optimistic in spite of biosimilar threat"[7] and J&J was urging investors to "stay calm" because "J&J has a 'readiness plan' in place for Remicade biosim launch."[8]

52. J&J's Biosimilar Readiness Plan utilized at least the following three means of exclusionary contracting to inhibit competition from Remicade biosimilars.

1. Biosimilar-exclusion contracts at the insurer level.

53. J&J imposed exclusionary contracts on insurers covering a significant portion of the United States market. These exclusionary contracts were designed to block infliximab biosimilars from gaining insurance coverage by either directly excluding Remicade biosimilars or imposing contractual conditions that effectively achieved the same result.

54. For example, in response to J&J's requests, some insurers instituted a medically unnecessary "fail first" exception, which requires that Remicade has been tried and failed with respect to a given patient before a biosimilar infliximab product can be reimbursed. The spurious nature of J&J's "fail first" restriction is illustrated by the fact that in early 2017, before J&J's contracts fully took hold, some major insurers listed the biosimilar Inflectra at parity with Remicade for coverage purposes, indicating that they saw no medical reason to favor one over the other. J&J's spurious "fail first" contractual requirement has the same practical effect as a purely exclusive contracts.

55. J&J imposed such exclusionary contracts on insurers as a means of excluding

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[7] Jacob Bell, *J&J optimistic in spite of biosimilar threat*, BIOPHARMA (Oct. 18, 2016), *available at* https://www.biopharmadive.com/news/jj-optimistic-in-spite-of-biosimilar-threat/428539/.

[8] Arlene Weintraub, *Stay calm, investors. J&J has a 'readiness plan' in place for Remicade biosim launch*, FIERCEPHARMA (Oct. 18, 2016), *available at* https://www.fiercepharma.com/pharma/j-j-drug-sales-soar-q3-but-remicade-biosimilar-looms.

lower-priced biosimilar competitors to Remicade. As discussed above, providers are unlikely to purchase an infliximab product that they are not confident will be reimbursed. Thus, J&J's effort to block infliximab biosimilars from attaining insurance coverage was designed to impede infliximab biosimilars' ability to achieve sales as the provider level.

56. Further, the foreclosure created by J&J's exclusionary contracts goes beyond the patients covered by certain insurers. Insurer coverage status for Remicade and its biosimilars (*e.g.*, Inflectra, Renflexis) has a spillover effect on the purchasing decisions of healthcare providers (as noted, the clinics, hospitals, and other institutions that purchase and administer infliximab) as well as the prescribing decisions of physicians affiliated therewith. Given the widespread gaps in infliximab biosimilar insurance coverage—engineered by J&J—providers have overwhelmingly chosen to stock *only* Remicade (which is essentially universally covered given its long tenure and dominant position) rather than deal with the risk of possible denials of coverage for infliximab biosimilars. Thus, many providers have declined to purchase infliximab biosimilars across the board, even for patients covered by insurance plans that *do* cover the product.

57. Additionally, J&J's rebates to providers were often volume-dependent, which exacerbated the anticompetitive effects of J&J's exclusionary contracts.

58. On top of all of this, J&J has stoked providers' reluctance to purchase infliximab biosimilars by touting with providers the very lack of coverage for infliximab biosimilars created by J&J's own exclusionary contracts.

2. Bundling of "contestable" and "incontestable" demand at the insurer level.

59. A key point of leverage that J&J has over insurers is the ability to deny rebate payments to insurers that decline J&J's exclusionary contracts. In effect, J&J says to insurers, "if you want to receive attractive rebates on Remicade for all your existing Remicade patients" - rebate

payments which, for some insurers, run into the many millions of dollar annually - "you must agree to not reimburse for competing biosimilar versions of infliximab, or to do so only in the most limited of circumstances." Thus, insurers that decline J&J's exclusionary contracts face a substantial financial penalty, and those that accept the contracts receive a payoff (rebate payments) in return for their commitment to insulate Remicade from competition.

60. J&J's threatened financial penalty of withholding rebate payments if insurers reimburse for any infliximab product other than Remicade is especially effective because Remicade is often used on a routine basis by many patients. Thus, a large number of patients are already controlling their chronic conditions with Remicade and are less likely to switch to a lower-priced biosimilar infliximab product (the "stable therapy patients"). This existing Remicade patient group represents demand for infliximab products that is more difficult for new entrants in the Infliximab Market (defined *infra* at ¶124) to win. These types of customers are referred to in economics as "incontestable demand" for a product.

61. As the head of J&J's pharmaceuticals business told investors during the October 2016 investor call: "the 70% of patients who are stable on Remicade are highly unlikely to switch."

62. J&J's exclusionary contracts bundle incontestable demand for infliximab with the portion of demand that is more readily contestable for biosimilar products - "new, restart, and switch" patients who are starting therapy with infliximab by threatening to deny rebates on *all* Remicade prescriptions if *any* infliximab biosimilar prescriptions are reimbursed.

63. A recent article by two Yale Medical School professors in the Journal of the American Medical Association illustrates how the kind of leverage J&J has over existing stable

Remicade patients allows it to extract commitments to exclude biosimilars.[9]

64. J&J's exclusionary contracts include bundling of contestable and incontestable demand at the insurer level as a mechanism of excluding lower-priced biosimilars. Further, such bundling of contestable and incontestable demand also makes it even less likely that providers will stock more than one infliximab product.

3. Multiproduct bundling at the insurer and provider levels.

65. As J&J has publicly acknowledged, J&J also bundles rebates on J&J's Remicade with multiple *different* drugs and medical devices in J&J's "robust portfolio" (*e.g.*, other non-infliximab products), such that insurers and providers that refuse to grant exclusivity to Remicade would be forced to pay higher prices or forego enhanced rebates on multiple J&J products.

66. J&J's multiproduct bundling of Remicade and other J&J products forecloses competitors like Samsung and Pfizer from competing with J&J's Remicade product because Pfizer and Samsung do not offer all of the products included in J&J's multiproduct bundling.

67. Thus, J&J's exclusionary contracts include multiproduct bundling and rebating at the insurer and provider level as a mechanism of excluding lower-price biosimilars.

C. J&J's Biosimilar Readiness Plan has been Remarkably Effective at Stifling Competition.

68. The combined effect of J&J's various biosimilar-exclusion contracting practices has been to inhibit competition from Remicade biosimilars.

69. For example, both Pfizer and Samsung set their initial list price, often referred to

[9] Aaron Hakim & Joseph S. Ross, *Obstacles to the Adoption of Biosimilars for Chronic Diseases*, JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (May 1, 2017), *available at* http://jamanetwork.com/journals/jama/article-abstract/2625049.

as the wholesale acquisition cost (WAC),[10] at below the then-current WAC of Remicade: Inflectra launched at a 15% discount to Remicade's WAC, and Renflexis launched at a 35% discount to Remicade's WAC. Yet, because J&J has retained its pricing power in the Infliximab Market, J&J has boosted Remicade's price in 2016 and 2017, and J&J still has over 90% market share in the Infliximab Market.

70. J&J is aware that its Biosimilar Readiness Plan has had its intended effect. J&J noted during May 2017 and July 2017 investor presentations that it had not "seen much of an impact" from infliximab biosimilar entrance[11] and that J&J is "especially well-prepared to manage through the Remicade biosimilars" in part because "we have our contracting in place with all the managed care organizations [*e.g.*, health insurers]."[12]

71. According to Pfizer, today, almost no national commercial health insurer provides coverage for competing biologic versions of infliximab (except under the spurious "fail first" scenario). To take one example, even though Inflectra is covered by Medicare and other government programs, providers have been unwilling to stock Inflectra even for potential use with such government-insured patients. As a result, not only is the federal government forced to continue reimbursing for Remicade, the more expensive product, but the effective foreclosure of biosimilars is expanded well beyond the 70% of commercially insured patients directly foreclosed by J&J's insurer contracts. Indeed, as of September 1, 2017, about *90%* of healthcare provider accounts using infliximab had purchased *no biosimilar product at all*.

72. As a Pfizer executive commented on a recent earnings call: "J&J's anti-

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[10] WAC is the manufacturer's published list price to wholesalers or direct purchasers, not including prompt pay or other discounts, rebates or reductions in price.

[11] J&J Presents at 2017 UBS Global Healthcare Conference Transcript (May 23, 2017).

[12] J&J Q2 2017 Earnings Call Transcript (July 18, 2017).

competitive practices concerning Remicade have denied patients and the broader United States healthcare system the benefits of robust price competition and therapeutic options in the biologics marketplace."[13]

73. The effects of J&J's Biosimilar Readiness Plan have also made headlines. For example, Bloomberg has reported on the issue, noting that Ascension Health, a nearly 23,000-bed nonprofit hospital system based in St. Louis, spends $55 million a year on J&J's Remicade, more than any other drug.[14] "Using Inflectra, part of a new class of medicines called biosimilars, would save it at least $10 million annually, according to Ascension's chief pharmacist, Roy Guharoy." The article notes that Guharoy planned to integrate Inflectra into care more often until learning that insurers preferred to stay with Remicade. "This we did not expect," Guharoy said. "If the insurance companies force us to use the branded product, of course our hands are tied." USB Global Research noted the same constraints, stating that "contracting and coverage will play a greater role in driving choice of therapy than the preferences of physicians or patients."

74. As noted by an analyst at Sanford Bernstein: "Fancy footwork in J&J's U.S. marketing strategy made all the difference to the company's ability to hold on to market share."[15]

D. Pfizer's Allegations Concerning J&J's Biosimilar Readiness Plan

75. Pfizer recently filed an antitrust complaint in this District making similar

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[13] Pfizer Q3 2017 Earnings Call Transcript (Oct. 31, 2017).

[14] Jared Hopkins, *What's Harder Than Making Copycat Biotech Drugs? Selling Them*, BLOOMBERG (Aug. 15, 2017), *available at* https://www.bloomberg.com/news/articles/2017-08-15/what-s-harder-than-making-copycat-biotech-drugs-selling-them.

[15] *See, e.g.*, Arelene Weintraub, *As Johnson & Johnson holds off U.S. biosims, Remicade's European market share falls to 50%*, FIERCEPHARMA (Dec. 5, 2017), *available at* https://www.fiercepharma.com/corporate/j-j-s-success-stunting-remicade-biosimilar-competition-us-cushions-blow-europe-report.

allegations to those set forth above.[16] Pfizer alleges that: "The core features of [J&J's Biosimilar Readiness Plan] are exclusionary contracts that foreclose Pfizer's access to an overwhelming share of consumers, coupled with anticompetitive bundling and coercive rebate policies designed to block both insurers from reimbursing, and hospitals and clinics from purchasing, Inflectra or other biosimilars of Remicade despite their lower pricing."

76. Pfizer's complaint alleges that J&J's Biosimilar Readiness Plan consisted of the following components:

1. Pfizer alleges biosimilar-exclusion contracts at the insurer level.

77. Like Plaintiff, Pfizer alleges that J&J secured contractual commitments from insurers to exclude biosimilars from coverage under their plans.

78. According to Pfizer, J&J has induced most major health insurers—covering at least 70% of commercially insured patients in the United States—to impose outright bans on competing biosimilars' coverage or to adopt spurious requirements designed to achieve the same goal (*e.g.*, "fail first" requirements).

79. Pfizer alleges that shortly after Pfizer's Inflectra received FDA approval in April 2016, health insurers undertook reviews to determine whether there was a medical reason not to reimburse Inflectra or to disfavor it relative to other therapies such as Remicade. Following these reviews, several major health insurance companies - including at least Aetna, Anthem and UnitedHealthcare - classified Inflectra at parity with Remicade. This confirmed that there was no medical reason justifying a restrictive reimbursement policy toward Inflectra. It also meant that, for the time being, Inflectra would be reimbursed without restriction. As a result, the stage was set

[16] *Pfizer Inc. v. Johnson & Johnson and Janssen Biotech, Inc.*, No. 17-4180, ECF 1 (E.D. Pa.).

for Inflectra to begin competing head-to-head with Remicade on a level playing field – and for purchasers to begin receiving the benefits of greater choice and lower prices. These circumstances changed quickly.

80. For example, in October 2016, UnitedHealthcare, the nation's largest health insurer, with more than 30 million covered commercial medical patients, published an update to its medical and site-of-care policies classifying Inflectra at parity with Remicade for the approved indications (with an effective date of November 1, 2016). This meant that, for UnitedHealthcare, Inflectra would be reimbursed freely and would not be disfavored relative to Remicade.

81. Just weeks later, however, Pfizer alleges that UnitedHealthcare reversed course. UnitedHealthcare classified Remicade as its "preferred" product and instructed that Inflectra would be eligible for reimbursement only in circumstances so limited as to be practically non-existent. Under UnitedHealthcare's new policy, Inflectra could be reimbursed only where the following conditions were met: (a) the patient must show a minimal clinical response, or an intolerance or adverse reaction, to Remicade; (b) the physician must attest that Inflectra would not lead to the same adverse responses; and (c) the patient must show no loss of favorable response in established maintenance therapy with Remicade and must not have developed neutralizing antibodies to any infliximab biosimilar product that has made the therapy less effective. As a practical matter, this meant that Inflectra, a drug the FDA approved as having no clinically meaningful differences in safety and efficacy, would not be reimbursed for UnitedHealthcare's more than 30 million commercial medical members and that Remicade would be the exclusive infliximab with UnitedHealthcare – despite the lack of any medical basis for denying those members access to a lower-priced alternative to Remicade. According to Pfizer, this change occurred after J&J induced UnitedHealthcare to enter into an exclusive deal by threatening to

penalize UnitedHealthcare with the loss of significant rebates unless UnitedHealthcare agreed to deny coverage of Inflectra.

82. According to Pfizer, J&J has employed the same approach to secure exclusive deals with a substantial number of other national and regional insurers who collectively cover approximately 114 million commercial medical patients of the approximately 214 million patients covered by commercial medical insurance in the United States.

83. For example, other national insurers such as Cigna adopted spurious "fail first" requirements designed to block competition to Remicade, while Anthem excluded Inflectra all together, and Aetna has adopted a complex set of rules that operated in practice like the "fail first" requirements of Cigna and UnitedHealth.

84. Other regional insurers also adopted "fail first" requirements. Pfizer alleges that at least HealthNet (Centene), CareFirst/Blue Cross Blue Shield, Blue Cross Blue Shield of North Carolina, Blue Cross Blue Shield of Tennessee, Blue Cross Blue Shield of Louisiana, Excellus Blue Cross Blue Shield, and Independence Blue Cross each adopted "fair fail" requirements.

85. In most cases these coercive biosimilar-exclusion contracts were the only economically viable option for insurers - as adopting any alternative would require the insurer to incur a substantial penalty (*i.e.*, foregoing rebates to existing Remicade patients) that could not be offset by the per-unit cost savings available on the number of patients likely to use the biosimilar, at least in the near term.

86. J&J's biosimilar-exclusion contracts were designed to inhibit competition from Remicade biosimilars.

87. Pfizer also alleges that J&J uses the gaps in insurance coverage, caused by J&J's conduct, to foreclose Inflectra from competing at the provider level. For example, J&J touts the

excluded status of Inflectra in its marketing communications, knowing that doing so will discourage providers from stocking the new biosimilar. J&J markets the "fail first" requirement as a selling point, despite the fact that such a provision is medically inappropriate and despite the FDA's determination that there are no clinically meaningful differences between the two products. J&J touts that Remicade is "Preferred Over Inflectra . . . Inflectra requires trial and failure on Remicade prior to [Inflectra] utilization."

88. Thus, given the widespread gaps in Inflectra's insurance coverage – caused by J&J – providers using infliximab have overwhelmingly chosen to stock only Remicade (which is essentially universally covered given its long tenure and dominant position), rather than deal with the risk of possible denials of coverage for Inflectra. Providers have declined to purchase Inflectra across the board, even for patients covered by commercial or government insurance plans that do cover the product.

89. The effective foreclosure of biosimilars thereby is expanded well beyond the 70% of commercially insured patients directly foreclosed by J&J's insurer contracts. Indeed, as of September 1, 2017, about 90% of healthcare provider accounts using infliximab had purchased no Inflectra at all.

90. As summarized during a recent Pfizer earnings call: "Due to J&J's exclusionary contracting, lower priced Inflectra has largely not received commercial access at parity to Remicade and remains disadvantaged."[17]

91. Pfizer also alleges that J&J also uses other means to maintain and enhance its monopoly, and to amplify the anticompetitive effects of J&J's contracts.

[17] Pfizer Q3 2017 Earnings Call Transcript (Oct. 31, 2017).

2. Pfizer alleges bundling of contestable and incontestable demand at the insurer level.

92. As discussed above, J&J is able to effectively leverage its large base of existing patients who are stabilized on Remicade and thus unlikely to switch (the incontestable demand) to block competition for new patients who may be candidates for infliximab (the contestable demand). And given J&J's long-standing monopoly in the Infliximab Market, its existing base of long-term patients is substantial and, for all intents and purposes, incontestable, despite the FDA's approval for use of biosimilars for all such patients.

93. Pfizer alleges that it and other biosimilar manufacturers focus their efforts on the contestable demand - new patients who may be candidates for infliximab - by pricing Inflectra competitively with both insurers and providers on a unit-for-unit basis. The fact that Inflectra's list price is more than 15% lower than Remicade's, and that Renflexis went to market at a price 35% below Remicade's, underscores the cost savings available.

94. Pfizer alleges that, to counteract this price competition, J&J threatened to withhold attractive rebates on all Remicade prescriptions - including those for existing patients as well as new ones - unless an insurer agreed to exclusivity. This way J&J is able to bundle the incontestable demand with contestable demand for Remicade to exclude competition for the contestable demand. Even if Pfizer offers a significantly lower price for Inflectra unit-for-unit, as it has done, insurers will agree to J&J's exclusive deals to avoid losing rebates on the substantial base of existing Remicade patients who are not likely to switch to Inflectra despite the presence of the lower-priced biosimilar.

3. Pfizer alleges multiproduct bundling and rebating at the insurer and provider levels.

95. Pfizer alleges that J&J has also insulated Remicade from competition through

multiproduct bundling at the insurer and provider level by bundling rebates for J&J's Remicade with rebates on other J&J drugs and medical devices.

96. Pfizer alleges that J&J has threatened insurers with the loss of rebates on other widely-used J&J drugs and medical devices, as well as J&J's Remicade, if they do not agree to exclude Inflectra from coverage.

97. Pfizer also alleges that J&J used multiproduct bundling in provider contracts conditioning rebates linked to other J&J drugs and medical devices upon a promise not to purchase infliximab biosimilars. As one analyst reported, J&J "bundled several drugs and medical devices together for larger hospitals, making Inflectra less economical."[18]

E. Pfizer Alleges that J&J's Biosimilar Readiness Plan has been Remarkably Effective at Stifling Competition.

98. According to Pfizer, J&J's multiproduct bundling, along with its bundling of contestable demand and incontestable demand, has amplified the anticompetitive effects of J&J's biosimilar-exclusion contracts and made the exclusivity provided by those contracts even more durable. Pfizer alleges that insurers have made it clear that Pfizer's net cost for Inflectra would need to be low enough to offset the loss of all J&J rebates. But because of the combined effect of these bundles Pfizer cannot offset the financial penalties that J&J threatens to impose on insurers who do not agree to exclusivity. As a result, Pfizer alleges that it is economically prohibited from competing for coverage by the major insurers – even when their exclusive contracts with J&J expire. Conditioning rebates linked to other J&J products not sold by J&J's Remicade competitors upon a promise not to do business with Inflectra only exacerbates the exclusionary nature of J&J's

[18] Aaron Gal, *Biosimilars: So, Why Has Remicade Biosimilar Not Gotten Much Traction in the U.S.*, BERNSTEIN RESEARCH (July 20, 2017).

contracts.

99. Meanwhile, Pfizer alleges that it is prepared to negotiate with providers to make Inflectra the lower priced infliximab option on a per-unit basis and has even offered to guarantee that Inflectra would be less expensive unit-for-unit than Remicade. But as with insurer contracts, to secure the right to deal freely with respect to Inflectra (*i.e.*, principally as to new patients), the providers would lose significant J&J rebates on their existing Remicade patient bases and on rebates from products not sold by J&J's competitors.

100. Thus, according to Pfizer, for Pfizer to make up the J&J rebates that insurers and providers would lose on their existing Remicade patients, Pfizer would have to price Inflectra below its own average variable cost. This is because the lost J&J rebates are based on the much larger base of existing Remicade patients, whereas Pfizer would be serving a much smaller group of new patients, at least in the near term.

101. Further, when the total amount of rebates that J&J offers to insurers and providers under the contracts described herein, including multiproduct bundle contracts, is attributed to the portion of Remicade sales that is contestable by a biosimilar like Inflectra, J&J is pricing Remicade below its own average variable cost. As a result, biosimilar competition to Remicade is foreclosed.

102. Altogether, Pfizer alleges that the combined effect of J&J's exclusionary scheme has been to foreclose Inflectra from approximately 90% of the provider account distribution channel essential to connecting Inflectra with patients of any kind.

VI. EFFECTS OF THE SCHEME ON COMPETITION AND DAMAGES TO PLAINTIFF AND THE CLASS

103. J&J's extensive infliximab biosimilar impairment efforts have proven beneficial for J&J. J&J continues to sell Remicade in the United States and, despite the entrance of biosimilar infliximab competitors, J&J has been able to maintain market share and raise prices for Remicade.

Absent J&J's unlawful scheme to impair infliximab biosimilar competition, infliximab products would have been priced lower.

104. J&J's anticompetitive scheme impaired the sale of infliximab products in the United States, and unlawfully enabled J&J to sell its branded Remicade infliximab product at artificially inflated prices. But for J&J's unlawful conduct, biologic competitors, such as Pfizer's Inflectra and Samsung's Renflexis, would have been able to compete, unimpeded, with their biosimilar infliximab products.

105. Further, an analyst at Sanford Bernstein noted that when prices for infliximab fell in Europe there was an uptick in infliximab usage: "Anecdotally, we have heard that patients are getting higher doses and we interpreted that to mean that therapy was rationed as costs come down, usage goes up."[19] Thus, J&J's exclusionary contracting scheme not only has a detrimental effect on competition, but also on the health and well-being of patients.

106. During the relevant period, RDC and other direct purchasers bought substantial amounts of infliximab products. As a result of J&J's unlawful conduct as alleged herein, RDC and other direct purchasers were compelled to pay, and did pay, artificially inflated prices for their infliximab product requirements. RDC and the other direct purchasers' prices for infliximab were substantially greater than the prices that they would have paid absent the unlawful conduct alleged herein.

107. As a consequence, RDC and other direct purchasers have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

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[19] *See, e.g.*, Weintraub *supra* n.8.

VII. CLASS ACTION ALLEGATIONS

108. Plaintiff brings this action in its own right and on behalf of all other similarly situated persons and entities under Federal Rules of Civil Procedure 23(a) and (b)(3), as defined below.

> All persons or entities that directly purchased infliximab in any form directly from one or more of the Defendants in the United States and its territories and possessions at any time during the period from April 1, 2016 until the anticompetitive effects of J&J's conduct cease (the "Class Period").
>
> Excluded from the Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, judicial officers and their personnel, and all federal governmental entities.

109. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes that there are dozens of Class members, geographically dispersed throughout the United States, such that joinder of all Class members is impracticable. Further, the Class members are readily identifiable from information and records maintained by Defendants.

110. Plaintiff's claims are typical of, and not antagonistic to, the claims of the other Class members, and there are no material conflicts with any other member of the Class that would make class certification inappropriate. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants.

111. Plaintiff will fairly and adequately protect and represent the interests of the Class and Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

112. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, including cases involving exclusionary contracts and bundling of pharmaceutical products.

113. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendants have acted on

grounds generally applicable to the entire Class. Thus, determining damages with respect to the Class as a whole is appropriate. The common applicability of the relevant facts to claims of Plaintiff and the proposed Class is inherent in Defendants' wrongful conduct, because the overcharge injuries incurred by Plaintiff and each member of the proposed Class arose from the same collusive conduct alleged herein.

114. The common legal and factual questions do not vary among Class members and may be determined without reference to individual circumstances, and include, but are not limited to, the following:

a. whether J&J intentionally and unlawfully impaired or impeded competition in the Infliximab Market;

b. whether J&J maintained or enhanced monopoly power in the Infliximab Market;

c. whether J&J engaged in anticompetitive conduct to unlawfully disadvantage its competitors and maintain monopoly power in the Infliximab Market;

d. whether J&J had procompetitive reasons for its conduct;

e. the effects of J&J's anticompetitive conduct on infliximab prices;

f. whether RDC and other members of the proposed class have been overcharged and thus damaged by paying artificially inflated prices for infliximab as a result of J&J's unlawful behavior;

g. the amount of the market foreclosed by J&F's anticompetitive practices; and

h. the proper measure of damages.

115. Treatment as a class action is the superior method for the fair and efficient adjudication of this controversy, as it will permit numerous similarly situated persons or entities to prosecute their common claims in a single forum simultaneously, avoiding unnecessary

duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding as a class action, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs any potential difficulties in management of this class action.

116. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VIII. EFFECT ON INTERSTATE COMMERCE

117. At all relevant times, J&J distributed, sold and will sell Remicade (infliximab) in a continuous and uninterrupted flow of commerce across state lines.

118. At all relevant times, J&J transmitted funds, as well as contracts, bills, and other forms of business communications and transactions pertaining to Remicade were transmitted in a continuous and uninterrupted flow across state lines in the exchange of interstate commerce.

119. J&J employed various instrumentalities to effectuate the unlawful acts alleged herein, including United States mail, interstate and foreign travel, and interstate and foreign telephone commerce, during all relevant times. Defendants' activities, as alleged in this Complaint, were within the flow of and have substantially affected interstate commerce.

IX. MONOPOLY POWER AND MARKET DEFINITION

120. Monopoly power is the ability of a single seller to raise prices above the competitive price level without losing significant business.

121. Direct evidence demonstrates that J&J was able to control prices and exclude relevant competitors.

122. At all relevant times J&J had monopoly power in a market limited to infliximab because it had the power to raise or maintain the price of Remicade at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable. Indeed, for years before

Inflectra's entry, J&J's prices for Remicade increased, yet Remicade did not lose unit sales. Between 2007 and 2017, Remicade's average sales price (ASP) increased more than 62%. Despite Remicade's price hikes, unit sales of Remicade have actually grown 15% during the period from 2012 to 2016.

123. Due to the challenged conduct, the introduction of competing biosimilar infliximab products has not eroded Remicade's monopoly power. For example, since Inflectra was launched, Remicade's prices have increased without affecting its market position. Ten months after Inflectra's introduction, Remicade still accounted for approximately 96% of United States infliximab sales. Absent the challenged conduct, Remicade would lose unit sales to other infliximab products.

124. To the extent that RDC and the proposed class of direct purchasers may be required to prove market power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant product market is the market for infliximab products (the "Infliximab Market"). This market currently consists of infliximab products marketed under the names Remicade, Inflectra, and Renflexis, as well as the recently approved Ixifi.

125. As alleged herein, infliximab is a unique biologic compound, which is approved for the treatment of various conditions. For example, J&J considers Remicade and FDA-approved biosimilars to be substitutes. This is evidenced by J&J's own marketing materials, which focus on comparisons of price and clinical effectiveness between Remicade and infliximab biosimilars. They do not reference any other drugs, and J&J's "Biosimilar Readiness Plan" similarly ignores other drugs, focusing instead on the unique competitive threat posed by biosimilars.

126. Functional similarities between Remicade and non-infliximab products are insufficient to permit inclusion of those other products in the Infliximab Market with Remicade.

To be an economic substitute for antitrust purposes, a functionally similar product must exert sufficient pressure on the prices and sales of another product, so that the price of that other product cannot be maintained at supracompetitive levels. No other products apart from biosimilar versions of Remicade could have taken away sufficient sales from Remicade and/or prevented J&J from raising or maintaining the price of Remicade at supracompetitive levels. Absent the conduct challenged in this case, only biosimilar versions of Remicade would have presented J&J with the choice of lowering price or losing unit sales.

127. A small but significant, non-transitory price increase in the price of Remicade did not cause, and would not cause, a significant loss of Remicade unit sales to drugs other than infliximab products. Remicade does not exhibit significant, positive cross-elasticity of demand with respect to price with any non-infliximab formulations or treatments and, absent the challenged conduct, would only exhibit such elasticity of demand with biosimilar versions of infliximab.

128. Absent the challenged conduct, Defendants would need to control only Remicade and its biosimilar equivalents, and no other products, in order to maintain the price of the products profitably at supracompetitive prices. Absent the challenged conduct, only the market entry of a competing, biosimilar version of Remicade would render Defendants unable to profitably maintain supracompetitive prices.

129. Defendants sold name-brand Remicade in excess of marginal costs, and in excess of the competitive price, and enjoyed unusually high profit margins.

130. At all relevant times, and in addition to the challenged conduct, Defendants enjoyed high barriers to entry with respect to the above-defined relevant market due to the regulatory difficulties that exist in obtaining FDA approval for a biosimilar drug.

131. Defendants' market share in the relevant market was and remains at or around

90% or greater throughout the Class Period.

132. The relevant geographic market is the United States and its territories.

X. CLAIMS FOR RELIEF

COUNT I

Violation of Section Two of the Sherman Act, 15 U.S.C. § 2
(Monopolization Through Exclusive Dealing Contracts)

133. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

134. At all relevant times, J&J possessed substantial market power (*i.e.*, monopoly power) in the relevant market. J&J possessed the power to raise and maintain supracompetitive prices and exclude competitors from the relevant market.

135. J&J has willfully maintained its monopoly power in the Infliximab Market through its exclusionary contracts and other anticompetitive means. As described in more detail above, J&J's Biosimilar Readiness Plan biosimilar-exclusion contracts leveraged, among other things, J&J's market power both in multiple products (including products not offered by J&J's Remicade competitors – *e.g.*, Pfizer and Samsung) and multiple sources of demand by imposing contractual terms on insurers and healthcare providers to prevent patients from having access to competing biosimilar versions of infliximab. Since at least April 2016, J&J's exclusionary contracts have unfairly impaired the ability of rival infliximab biosimilars to compete for market share and thereby preserved J&J's dominance and monopoly power in the market for infliximab.

136. By engaging in this conduct, J&J has gained an artificial and unlawful competitive advantage from its monopoly power and broad list of product offerings, instead of its lower price or superior quality, and unfairly impeded and impaired competition in the Infliximab Market. The purpose and effect of J&J's conduct has been to suppress rather than promote competition on the

merits.

137. By suppressing competition and maintaining monopoly power, J&J was able to artificially inflate the price of Remicade above levels that would have been obtained in a world in which J&J did not engage in the anticompetitive conduct alleged herein. Instead of lowering its price to meet new rivals, J&J's biosimilar-exclusion contracts allowed J&J to maintain and raise Remicade's price. Moreover, because J&J's conduct removed price cutting as an effective competitive response for competing biologic manufacturers, biosimilar infliximab product prices were higher than they otherwise would have been as well.

138. Accordingly, the challenged conduct caused Plaintiff and members of the proposed class to pay artificially inflated prices for infliximab sold into the private market.

139. There is no procompetitive justification for J&J's conduct.

140. Plaintiff has been injured in its businesses and property by reason of J&J's unlawful monopolization. Plaintiff's injuries consist of paying higher prices to purchase the relevant products than they would have paid absent J&J's conduct. Plaintiff's injuries are of the type the antitrust laws were designed to prevent and flow from that which makes J&J's conduct unlawful.

COUNT II

Violation of Section One of the Sherman Act, 15 U.S.C. § 1 (Contracts in Restraint of Trade)

141. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

142. As set forth above, J&J has used exclusionary contracts with insurers and healthcare providers to preserve and extend J&J's monopoly power in the Infliximab Market. J&J entered into agreements with insurers and healthcare providers to enforce its exclusionary scheme.

These agreements included written exclusionary agreements prohibiting J&J's customers from purchasing other infliximab products in unreasonable restraint of trade, which included various exclusionary contractual terms (*e.g.*, anticompetitive bundling at the insurer and provider levels, excluding infliximab biosimilars outright, and/or utilizing spurious "fail first" provisions to exclude infliximab biosimilars).

143. As alleged above, there was no legitimate business justification for these agreements and these agreements: (a) substantially foreclosed and excluded competition from competing infliximab manufacturers; and (b) resulted in J&J's willful maintenance and unlawful exercise of monopoly power in the Infliximab Market.

144. At all relevant times, J&J's exclusionary agreements assisted J&J in: (a) effectively excluding less expensive competitive products from the Infliximab Market; (b) maintaining J&J's dominant market share and monopoly power in the Infliximab Market; (c) maintaining prices at artificially high levels for infliximab; and (d) otherwise reaping the benefits of its illegal monopoly power.

145. There is no procompetitive justification for J&J's conduct.

146. Plaintiff has been injured in their businesses and property by reason of the alleged collusion and conspiracy, which facilitated, enabled, assisted, and furthered J&J's substantial foreclosure and exclusion of competition and monopolization of the Infliximab Market. Plaintiff's injuries consist of paying higher prices to purchase the relevant products than they would have paid absent J&J's unlawful conduct. Plaintiff's injuries are of the type the antitrust laws were designed to prevent and flow from that which makes J&J's conduct unlawful.

XI. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on behalf of itself and the Class, respectfully requests that the Court:

a. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the Class, and declare the Plaintiff as the representative of the Class;

b. Enter joint and several judgments against Defendants and in favor of Plaintiff and the Class;

c. Award the Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial;

d. Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

e. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XII. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiff on behalf of itself and the proposed Class, demands a trial by jury on all issues so triable.

Dated: January 24, 2018

Respectfully submitted,

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